

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | F | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------|-----------------------|--------------|----------------------|-------------------------|------------------|
| 09/943,193 | 09/943,193 08/29/2001 | | Kenneth M. Riff | P-9618.00 | 8485 |
| 27581 | 7590 | 10/20/2003 | | EXAMINER | |
| MEDTRO | | | FRENEL, VANEL | | |
| 710 MEDTRONIC PARKWAY NE MS-LC340 | | | ART UNIT | PAPER NUMBER | |
| MINNEAP | OLIS, MN | N 55432-5604 | 3626 | | |
| | | | | DATE MAILED: 10/20/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | | |
|--|---|---|---|--|--|--|--|--|
| | Office Action Summan | 09/943,193 | RIFF ET AL. | | | | | |
| • | Office Action Summary | Examiner | Art Unit | | | | | |
| | , | Vanel Frenel | 3626 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| THE I - Exter after - If the - If NO - Failu - Any r | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period we re to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | is(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | ety filed s will be considered timety. the mailing date of this communication. O (35 U.S.C. § 133). | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 21 J | <u>uly 2003</u> . | | | | | | |
| 2a)⊠ | This action is FINAL . 2b) Thi | s action is non-final. | | | | | | |
| 3) 🗌 | | | | | | | | |
| Dispositi | on of Claims | | | | | | | |
| 4)⊠ | Claim(s) <u>1-21,32-47 and 66-74</u> is/are pending | in the application. | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ | Claim(s) <u>1-21,32-47 and 66-74</u> is/are rejected. | | | | | | | |
| 7) 🗌 | Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. Application Papers | | | | | | | | |
| 9) 🔲 🤈 | The specification is objected to by the Examiner | <i>r</i> . | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | | |
| Attachmen | | | | | | | | |
| 2) Notic | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal F | (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | | |
| S Patent and T | and a most Office. | | | | | | | |

'Art Unit: 3626

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Amendment filed 07/21/03. Claims 33, 39-44, 47 and 68 have been amended. Claims 1-21, 32-47 and 66-74 are pending.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 33, 35, 39-44, 47 and 68 are rejected under 35 U.S.C. 103(a) as being who will come ((, |0|, u.Y)) unpatentable over Albert et al (6,264,614) in view of Sato et al (5,911,687), for substantially the same reasons given in the previous Office Action (Paper number 7). Further reasons appear hereinbelow.
- (A) Claim 33 has been amended to now recite "enabling the database network site to communicate with at least one web-enabled web-site and to receive web-site originated signals requesting access to the database". As per this feature, Albert discloses Using the computer 10 (e.g., personal computer 16) where the patient is located, the Internet site having the medical data acquisition and transmission program is accessed from the respective patient's site. Access occurs by the computer 10 at the patient site 2 running its web browser or otherwise gaining access to the Internet 4. Once Internet access has been gained, the computer 10 accesses the known log-on site where the medical data

Art Unit: 3626

One of ordinary skill in the art at the time of the invention would have found obvious to modification to include the feature of sato within the system of Albert with the motivation of including a personal computer programmed with a web browser and a medical data acquisition and transmission program. The medical data acquisition and transmission program can be downloaded from an Internet site accessed using the web browser (See Albert, Col.3, lines 14-19).

The remainder of claim 1/1s rejected for the same reasons given above in the previous Office Action. (Paper number 7), and incorporated herein.

Application/Control Number: 09/943.193 Page 4

Art Unit: 3626

The amendment to claims 35, 39-44, 47 and 68 reflect the same change made to (B) claim 33, and are therefore rejected for the same reasons given above for claims 35. 39-44, 47 and 68 in addition to the reasons given in the prior Office Action (Paper Claims 1-21 réjected under Albert & Sato number 7), and incorporated herein.

Claims 1-21, 32, 36,38, 45-46, 66-67 and 69-74 have not been amended and are (C) rejected for the same reasons given in the previous Office Action (Paper number 7), and incorporated herein.

Response to Arguments

- 4. Applicant's arguments filed on 07/21/03 with respect to claims 33,35, 39-44,47 and 68 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed on 07/21/03.
- At pages 17-22 of the 07/21/03 response, Applicant argues the followings: (A)
- (1) Albert does not disclose a "pay for use" system wherein monitoring data packages to determine revenue for the service is performed.
- (2) Albert does not disclose the enabling of a database network site to communicate with at least one web-enabled web-site to receive web-site originated signals requesting access to the database of stored physiological data.
- (3) The combination of Albert and Sato fails to provide the subject matter of claim 1 and the obviousness rejection necessarily fails as a result.

'Art Unit: 3626

- (4) There is no suggestion from Krichen to use Albert to acquire data from a patient with an IMD, the combination of Albert and Krichen does not result in the subject matter of claim 32.
 - (5) There is no motivation to combine Albert and Brown.
- (B) With respect to Applicant's first argument, Examiner respectfully suggests that Sato discloses "When the doctor in the clinic 102 of the electronic hospital determines that dosage of a drug for a patient is necessary, he performs the following process. The doctor gives an order of prescription to the pharmacy (generally the nearest pharmacy 103 to the patient's house 101) designated by the patient and outputs the prescription online. The pharmacy 103 prepares a medicine according to the output prescription. In this case, on request by the patient, the medicine may be delivered to the patient's house. When the doctor in the clinic 102 of the electronic hospital determines that physical measures such as examination and treatment are necessary for the patient, he performs the following process. The doctor gives various orders to the treatment center 105 designated by the patient online. Therefore, the patient 101 can receive the necessary measures at the treatment center 105. The treatment center of the present invention is not necessary to be a dedicated one of the electronic hospital. For example, it may be an existing hospital. Furthermore, the treatment fee is paid as shown below. When the examination and treatment end, the doctor in the clinic 102 asks the financial institution 106 where the patient's deposit account exists to pay the treatment fee to the patient 101. The financial institution 106 automatically withdraws the treatment fee from

Art Unit: 3626

the deposit account of the patient on the fixed date every month" which correspond to Applicant's claimed feature (See Sato, Col.5, lines 59-67 to Col.6, line 17). Therefore, Applicant's argument is not persuasive.

(C) With respect to Applicant's second argument, Examiner respectfully suggests that Albert discloses "The method of the present invention for the foregoing embodiments is now described with reference to FIG. 6. Using the computer 10 (e.g., personal computer 16) where the patient is located, the Internet site having the medical data acquisition and transmission program is accessed from the respective patient's site. Access occurs by the computer 10 at the patient site 2 running its web browser or otherwise gaining access to the Internet 4. Once Internet access has been gained, the computer 10 accesses the known log-on site where the medical data acquisition and transmission program is located. This can be the site through which Internet access is gained, or the site containing the medical data acquisition and transmission program can be different from the Internet portal. When the appropriate site has been accessed, identification information (e.g., name, password) is entered (e.g., manually by the patient or automatically by preprogramming the patient's computer 10) to enable the computer 10 at the patient site 2 to select and download the medical data acquisition and transmission program. When the appropriate information has been given to the logon site 6a in the illustrated embodiments of FIGS. 3 and 4, the medical data acquisition and transmission program downloads to, or otherwise becomes accessible for use by, the computer 10 at the patient site 2. The medical data acquisition and transmission

Art Unit: 3626

program preferably downloads in active mode so that it is ready to perform the functions at the patient site 2 without the patient having to perform functions other than manipulating the sensor to sense the biological function or condition to be transmitted to the computer 10 at the patient site. In the implementation of FIG. 5, the patient 12 holds the heart monitor 8 against his or her chest. The heart monitor 8 responds to the beating heart by generating corresponding acoustical signals transmitted to the microphone 14. The microphone 14 converts the signals to analog electric signals communicated to the personal computer 16 programmed with the downloaded medical data acquisition and transmission program. In using the medical data acquisition and transmission program, the personal computer 16 receives the signals, processes the received signals, and transmits medical data signals onto the Internet 4 in response. Transmitting over the Internet 4 to a recipient site 6b includes accessing a second Internet site from the computer 10 and transmitting patient data over the Internet to the accessed second Internet site 6b, both under control of the medical data acquisition and transmission program used by the computer 10. In addition to the foregoing which is illustrated in FIG. 6, the method of the present invention can further comprise receiving, over the Internet, the transmitted medical data signals at a recipient site. As explained above, this can be any suitable site, such as a medical facility or a data communication service provider facility. The former would typically be an end user of the data whereas the latter would typically be an intermediary that transfers the data onto an end user. As explained above with reference to FIG. 4, such could include transmitting, from the data communication server provider facility to an end user, end user signals responsive to

Art Unit: 3626

the received medical data signals. In FIG. 4, this includes transmitting the medical data signals through the wireless data network 24" which correspond to Applicant's claimed feature (See Albert, Col.8, lines 6-67). Therefore, Applicant's argument is not persuasive.

(D) With respect to Applicant's third to fifth arguments, Examiner respectfully suggests the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references.

Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed.1326, 160 USPQ 806, *In re Kell, Terry and Davies* 208 USPQ 871; and In *re Fine*, 837 F. 2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir.1988) citing In *re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

- (i) obviousness does not require absolute predictability;
- (ii) non-preferred embodiments of prior art must also be considered; and

¹ Art Unit: 3626

(iii) the question is not express teaching of references, but what they would suggest.

Examiner respectfully submits, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 07/21/03 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Albert, Sato, Krichen and/or Brown, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck* & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3626

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches method and system for remotely monitoring multiple medical parameters in an integrated medical monitoring system (6,364,834), system and method for managing patient care (US 2002/0169636) and real time ambulatory patient monitor (5,544,661).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9643. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

- * Art Unit: 3626

October 17, 2003

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3600